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10/627,271	07/25/2003	Earl A. Hubbell	3246.2	7605

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EXAMINER	
WHALEY, PABLO S	

ART UNIT	PAPER NUMBER
1631	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/627,271	HUBBELL, EARL A.	
	Examiner	Art Unit	
	Pablo Whaley	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4-14 and 25-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4-14 and 25-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' remarks, filed 04/23/2007, have been fully considered. The following rejections and/or objections are maintained, newly applied, or withdrawn for the reasons set forth below. They constitute the complete set presently being applied to the instant application.

APPLICANT'S ELECTION REITERATED

Applicant's election without traverse of Claims 4-14 and 25-33 (Group II) and Species (i), directed to oligonucleotides, in the reply filed on 08/25/2006 is acknowledged.

CLAIMS UNDER EXAMINATION

Claims 4-14 and 25-33 are herein under examination, as they read upon the elected specie of polymer directed to oligonucleotides. Claims 1-3, 15-24, and 34-40 have been cancelled.

OBJECTIONS

The Specification has been amended and is now acceptable.

CLAIM REJECTIONS - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 4-14 remain rejected under 35 U.S.C. 101 because these claims are drawn to non-statutory subject matter.

Applicant's arguments that the Guidelines do not require an actual concrete, tangible, and useful result to be recited in the claims are not persuasive. A "claimed" invention that encompasses non-statutory subject matter and does not recite a practical application of a 35 U.S.C. 101 Judicial exception is rejected under 35 USC 101. The Examiner maintains the above rejection is appropriate for the following reasons. This rejection is maintained and reiterated.

Claims 4-14 are directed to a computer implemented method for arranging polymers. According to the revised Guidelines, a claimed invention directed to a statutory process must provide: (1) a practical application by physical transformation (i.e. reduction of an article to a different state or thing), or (2) a practical application that produces a concrete, tangible, and useful result [State Street Bank & Trust Co. v. Signature Financial Group Inc. CAFC 47 USPQ2d 1596 (1998)], [AT&T Corp. v. Excel Communications Inc. (CAFC 50 USPQ2d 1447 (1999)]. The revised Guidelines also state that the focus is "not on whether the steps taken to achieve a particular result are useful, tangible, and concrete, but rather on whether the final result achieved by the claimed invention is useful, tangible, and concrete."

Claim 4 recites computer-implemented steps generally directed to reducing edge count, dividing polymers into blocks, selecting blocks, and assigning blocks to empty slots. The Examiner would like to emphasize that the claimed method does not recite any step directed to

synthesizing a polymer on a substrate or even *providing a substrate*. Therefore, the claimed methods steps may be achieved entirely *in-silico* (e.g. on a virtual substrate). As the specification does not define these steps such that they are physical method steps (i.e. done by a user), the instant claims do not result in a physical transformation of matter. Where a claimed method does not result in a physical transformation of matter, it may be statutory where it recites a result that is concrete (i.e. reproducible), tangible (i.e. real-world), and useful result (i.e. a specific and substantial). However, the claimed result (i.e. selecting a subset of the blocks) may occur *in-silico* and thus is not interpreted to be a tangible result that is useful to one skilled in the art. For the above reasons, the instant claims do not recite a practical application of a 35 U.S.C. 101 Judicial exception and therefore are not statutory.

This rejection could be overcome by amending the claims to recite a "tangible" (i.e. real-world result). For exemplary purposes only, applicant would likely overcome this rejection by amending the claims to recite one of the following: (1) a step wherein the result of the claimed method is communicated to a user (i.e. real-world result), graphically displayed, or output (e.g. to a user, to a memory, or to another computer); or (2) by amending the claims to include of a physical transformation of matter (e.g. assay). For an updated discussion of statutory considerations, see the revised Guidelines for Patent Eligible Subject Matter in the MPEP 2106, Section IV (Latest Revision August 2006).

CLAIM REJECTIONS - 35 USC § 112, 2nd Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4-14 and 25-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. *The following rejections are necessitated by amendment.*

Claims that depend directly or indirectly from claims 4 and 25 are also rejected due to said dependency.

Claims 4 and 25 now recite the limitation "assigning each of the unassigned block to an empty slot." It is unclear as to the meaning of "each of the unassigned block." The Examiner believes this may be a typographical error. Clarification is requested.

Claims 4 and 25 now recite the limitation "selecting a subset of the blocks from the plurality of unassigned blocks." As the previous step was directed to the assignment of each of the unassigned blocks, the above limitation is confusing, as it appears that all blocks have been assigned so it is unclear in what way one selects a subset of unassigned blocks. Applicant is encouraged to be consist with claim language with regards to *blocks*, *assigned blocks*, and *unassigned blocks*. Clarification is requested via clearer claim language.

Claims 4 and 25 now recite "creates an arrangement of polymers resulting in a least edge count among the subset of blocks." It is unclear in what way an arrangement of polymers results in a "least edge count", as the claims do not recite any step directed to obtaining "edge counts" or steps wherein arrangement of polymers are related to edge counts. Clarification is requested via clearer claim language.

Claim 6 now recites the limitation "by minimizing edge count slot." It is unclear as to the intended meaning of "edge count slot." Parent claim 4 recites "edge count" and "empty slots", but does not recite "edge count slot." Clarification is requested via clearer claim language.

Claim 7 now recites the limitation "comprising first selecting the subset among unassigned blocks." It is unclear as to the intended meaning of "first selecting", as the claims do

not recite any further selection steps that were serve to clarify the issue (i.e. second and third selecting).

CLAIM REJECTIONS - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C.102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 5, and 7-13 remain rejected under 35 U.S.C. 102 (b) as being unpatentable over Pease et al. (Proc. Natl. Acad. Sci., May 1994, Vol. 91, p.5022-5026).

Applicant's arguments that Pease et al. do not teach "assigning each unassigned block to empty slots on the substrate" are not persuasive for the following reasons.

Pease et al. clearly teach combinatorial synthesis methods wherein probes are coupled to a substrate surface [p.5025, Col. 1, ¶ 2] and [Fig. 4]. Synthesis areas (i.e. empty slots on the substrate) are activated by illumination to facilitate coupling (i.e. assignment) of nucleosides (i.e. unassigned blocks) [Fig. 4]. Therefore the Examiner maintains that Pease et al. teach "assigning each unassigned block to empty slots on the substrate."

Furthermore, Pease et al. teach the following aspects of amended claims 4, 5, and 7-13: A plurality of polymers for synthesis on a substrate [Fig. 3] and [p.5025, Col. 2]; nucleosides that have not yet been coupled (i.e. unassigned blocks) [Fig. 4]; arrangement of polymers via combinatorial synthesis of oligonucleotides using masks [p.5025, Col. 1, ¶ 2], wherein each

"round" results in a reduced distance between edges between oligonucleotides [Fig. 4], which equates to a "least edge count" and "minimizing edge count" as in claims 4, 11, 12, and 13. For the above reasons, and for reasons set forth in the previous office action, mailed 10/27/2006, the Examiner maintains that Pease et al. indeed describes all of the limitations of the instantly rejected claims. This rejection is therefore maintained.

Claims 4-6 and 25-27 remain rejected under 35 U.S.C. 102(b) as being anticipated by Li et al. (Genomics, 1997, Vol. 40, p.476–485).

Applicant's arguments that Li et al. does not teach "obtaining a list of polymers to be synthesized on the substrate" are not persuasive for the following reasons.

The Li et al. reference was applied to illustrate the broad nature of the claimed invention. The Examiner would like to emphasize that claims 4 and 25 now recite "obtaining a list of polymers to be synthesized on the substrate", which is an intended use of said polymers and is not an active method step (i.e. synthesizing). Therefore, prior art is not required to teach a step of "synthesizing polymers on a substrate." Claims 5 and 26 also now recite the limitation "for synthesis by minimizing edge count," which is an intended use and is also not an active method step (i.e. synthesizing). Therefore, prior art is not required to teach a step of "synthesizing." Regarding amended claims 4 and 25, Li et al. teach the following aspects of amended claims 4 and 25:

- Obtaining a list of oligonucleotides [p.480, Col. 2, ¶ 4] comprising both trial and accepted oligonucleotide primers [p.483, Col. 1, ¶ 1], which equates to assigned and unassigned blocks, as in claims 4 and 25.

- Dividing oligonucleotide primers into a plurality of regions (i.e. blocks), and selecting regions with sufficient quality [Fig. 1], as in claims 4 and 25.
- Reducing the gap between primer pairs via clipping [p.481, Col. 2, ¶ 1], which equates to "reducing edge count" as in claims 4 and 25.
- Assigning bases for primer design to positions on a template sequence (i.e. substrate) computing and comparing BQ scores to a threshold [p.478, Col. 2, ¶ 2] and [Fig. 2] and [Table 2], as in claims 4, 6, 25, and 27.
- Repeating methods assigning until appropriate primers are found [Fig. 3], as in claims 5 and 26.
- Code written in ANSI C and maintained in two versions for use with MAC and UNIX processors (Abstract), as in instant claim 25.

The Examiner maintains he has broadly and reasonably interpreted the claims to encompass the teachings of Li et al. For the above reasons, and for reasons set forth in the previous office action, mailed 10/27/2006, the Examiner maintains that Li et al. describes all of the limitations of the instantly rejected claims. This rejection is therefore maintained.

CLAIM REJECTIONS - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 6 is rejected under the first paragraph of 35 USC § 103(a) as being unpatentable Pease et al. (Proc. Natl. Acad. Sci., May 1994, Vol. 91, p.5022-5026), as applied to claims 4, 5, and 7-13, above, and further in view of Fodor et al. (Science, 1991, Vol. 251, p.767-773). *This rejection is necessitated by amendment.*

Pease et al. teach a method for arranging oligonucleotides on DNA chips for parallel DNA analysis [Abstract], as set forth above and applied to claims 4, 5, and 7-13.

Pease et al. do not specifically teach computing a plurality of edge counts, as in claim 6, or a computer program product as in claims 25 However, Pease et al. do suggest computation of intensity counts for a plurality of oligonucletide sequences [p.5025, Col. 1, ¶3 and Col. 2, ¶1].

Fodor et al. teach a method for arranging oligonucleotides on high density arrays using binary synthesis [Abstract]. More specifically, Fodor et al. teach the following aspects of the instant invention: computation of integers (i.e. edge counts) for a plurality of peptide sequences [p.769, Col. 1, 3 and Col. 2, 1], and matrix representation for assigning masks that generate desired products using said integers [p.769, Col. 1, ¶1 and ¶2], as in claim 6.

Thus it would have been obvious to one of ordinary skill in the art at the time of the invention to have practiced the method for arranging oligos on DNA chips taught by Pease et al. with the binary synthesis method for calculating "edge counts" as taught by Fodor et al., as both teach methods of arranging nucleotides on high density arrays. One of ordinary skill in the art would have been motivated to combine the above teachings to develop an improved parallel

synthesis method for analyzing large numbers of pharmaceutical compounds for use in drug therapy [p.772, Col. 1, ¶3] resulting in the practice of the instantly claimed invention. One of ordinary skill in the art would have had a reasonable expectation of successfully combining the above teachings as both clearly teach methods of chemical synthesis.

CONCLUSION

No claims are allowed.

Accordingly, THIS ACTION IS MADE FINAL. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pablo Whaley whose telephone number is (571)272-4425. The examiner can normally be reached on 9:30am - 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached at 571-272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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